

REMARKS

Claims 1-14 are pending in the present application. By virtue of this response, claims 13 and 14 have been cancelled, claim 1 has been amended and new claim 15 has been added. Accordingly, claims 1-12 and 15 are currently under consideration. Support for amendment of claim 1 is provided on page 10, paragraph [0041]; page 11, paragraph [0042]; and page 12, paragraph [0046]. Support for new claim 15 is provided on page 3, paragraph [0014]. Accordingly, no new matter has been added.

With respect to all claim amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in a future continuation and/or divisional application.

Objection to the use of trademark TAXOL

The Examiner objects to the specification for use of the trademark "TAXOL." The Examiner states that this word should be capitalized wherever it appears and be accompanied by the generic terminology.

In response, Applicant notes that he may be his own lexicographer. MPEP § 2111.01(IV) (8th ed. Rev. 5, Aug. 2006); *see In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Applicant's specification clearly defines "taxol" as referring to "paclitaxel (TAXOL®, Bristol-Myers Squibb Oncology, Princeton, NJ), docetaxel (TAXOTERE®, Rhône-Poulenc Rorer, Antony, France), and other taxanes. Taxol (including other taxanes) may be administered either alone, or in combination with other drugs." Paragraph [0045]. Thus, "taxol" is defined more broadly in the specification than as only referring to paclitaxel under the tradename TAXOL®. Based on Applicant's specification, one skilled in the art would readily appreciate the term "taxol" as used by Applicant refers to paclitaxel, docetaxel, and other taxanes. When the TAXOL® and TAXOTERE® trademarks are used in paragraph [0045], they are capitalized and accompanied by the generic term

paclitaxel or docetaxel, respectively, as required by the Examiner. In view of these clarifying remarks, this objection should be withdrawn.

Objection to the abstract

The Examiner states that the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR §1.52(b)(4), and a new abstract is required and must be presented on a separate sheet.

MPEP 1893.03(e) provides that the requirement of 37 CFR 1.52(b) that the abstract "commence on a separate physical sheet or electronic page" does not apply to the copy of the published international application communicated to the designated Offices by the International Bureau under PCT Article 20. Since this application is a national stage application based on a published PCT application, submitting the abstract on a separate sheet is not required. Accordingly, Applicant respectfully request that this objection be withdrawn.

Claim rejections under 35 U.S.C. §112, first paragraph

Claims 1-8, 13, and 14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the claims encompass use of an antibody which binds trkC from any animal species and it is unclear as to what species other than human or mouse trkC were known in the prior art. The Examiner concluded that the written description provided in the specification is not commensurate with the scope of the claimed inventions.

Applicant respectfully notes that claims 13 and 14 have been cancelled; and thus, the rejection to these claims becomes moot.

Without acquiescence to the rejection and in the interest of expediting prosecution, Applicant has amended claim 1 to recite that the agonist anti-trkC antibody binds to a mammalian trkC receptor and activates the trkC receptor. Applicant respectfully submits that claims 1-8 as amended satisfy the written description requirement.

The MPEP states, “[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.” MPEP §2163.II.A.3.(a)(ii) [emphasis added] Thus, reduction to practice alone, or disclosure of relevant identifying characteristics alone, is sufficient to satisfy the written description requirement. “Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.” MPEP §2163.II.A.2.

Applicant respectfully submits that several mammalian trkC were cloned and sequenced at the priority date of the present application. For example, the amino acid sequences of trkC from human (Gene Bank Accession No. AAB33112), pig (Gene Bank Accession No. AAA31130), and rat (Gene Bank Accession No. AAB26716) were published. With the information of these sequences and structural and functional similarities among different mammalian species, one skilled in the art could easily obtain the amino acid sequence of trkC from other mammals. Accordingly, the disclosure of the application conveys with reasonable clarity to those skilled in the art, as of the priority date, Applicant was in possession of the invention as claimed. Applicant respectfully submits that claims 1-8 as amended satisfy the written description requirement.

In view of the above, Applicant respectfully request that the rejection be withdrawn.

Claim rejections under 35 U.S.C. §112, second paragraph

Claims 1-14 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that claim 1 contains the trademark/trade name "taxol" and the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

As noted above, Applicant may be his own lexicographer. MPEP § 2111.01(IV). "Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim." *Id.* (citing *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999)). Applicant's specification defines "taxol" as "paclitaxel (TAXOL®, Bristol-Myers Squibb Oncology, Princeton, NJ), docetaxel (TAXOTERE®, Rhône-Poulenc Rorer, Antony, France), and other taxanes." Paragraph [0045]. Based on Applicant's specification, the term "taxol" as used by Applicant refers to paclitaxel, docetaxel, and other taxanes and is not limited to the trademark TAXOL®. Accordingly, this rejection should be withdrawn.

Claim Rejections under 35 U.S.C. §102

A. Claims 1-8 and 13 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Devaux *et al.* (WO 01/98361). The Examiner states that Devaux *et al.* teach the claimed pharmaceutical composition containing an agonist anti-trkC antibody (see claim 49) and the recitation of an intended use carries no patentable weight in the aforementioned claimed product. The Examiner further states that both the claimed invention and the teachings of Devaux *et al.* encompass administration of the same antibody to patients which are receiving taxol and do not yet have disease wherein the antibody would be administered at the time that the taxol was administered.

Applicant respectfully notes that claim 13 has been cancelled; and thus, the rejection to this claim becomes moot.

Applicant further notes that claim 1 (from which claims 2-8 depend) has been amended to recite that the anti-trkC agonist antibody is administered to a mammal having a taxol-induced gut disorder.

To anticipate a claim, a prior art reference must teach each and every element set forth in the claim. MPEP §2131. Applicant respectfully submits that Devaux *et al.* do not teach or suggest the claimed invention. In particular, Devaux *et al.* do not teach administering an anti-trkC agonist antibody to a mammal having a taxol-induced gut disorder. Devaux *et al.* also do not demonstrate that an anti-trkC agonist antibody can successfully treat taxol-induced gut disorder. Thus, Devaux *et al.* do not anticipate claims 1-8 as amended.

B. Claims 9-12 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Pons (WO 2005/062955). The Examiner states that the claims encompass treatment of a taxol receiving patient before onset of disease, and Pons teaches the antibody containing the sequences recited in the claims and it can be administered before the neuropathy inducing agent.

Applicant respectfully notes that claim 1 (from which claims 9-12 depend) has been amended to recite that the anti-trkC agonist antibody is administered to a mammal having a taxol-induced gut disorder.

To anticipate a claim, a prior art reference must teach each and every element set forth in the claim. MPEP §2131. Applicant respectfully submits that Pons does not teach or suggest the claimed invention. In particular, Pons does not teach administering an anti-trkC agonist antibody to a mammal having a taxol-induced gut disorder. Pons also does not demonstrate that an anti-trkC agonist antibody can successfully treat taxol-induced gut disorder. Thus, Pons does not anticipate claims 9-12 as amended.

In view of the above, Applicant respectfully requests that the rejections under 35 U.S.C. §102 be withdrawn.

Claim Rejections under 35 U.S.C. §103

Claims 1-8, 13, and 14 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Devaux *et al.* (WO 01/98361) in view of Ashkenazi *et al.* (US 6,252,050).

Applicant respectfully notes that claims 13 and 14 have been cancelled; and thus, the rejection to these claims becomes moot.

Applicant further notes that claim 1 (from which claims 2-8 depend) has been amended to recite that the anti-trkC agonist antibody is administered to a mammal having a taxol-induced gut disorder.

To establish a prima facie case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claimed limitations. MPEP §2143. As discussed above, Devaux *et al.* do not teach or suggest administering an anti-trkC agonist antibody to a mammal having a taxol-induced gut disorder. Devaux *et al.* also do not demonstrate that an anti-trkC agonist antibody can successfully treat taxol-induced gut disorder. Ashkenazi *et al.* do not cure this deficiency of Devaux *et al.* Ashkenazi *et al.* do not teach or suggest administering an anti-trkC agonist antibody to a mammal having a taxol-induced gut disorder. Since Devaux *et al.* and Ashkenazi *et al.*, even if combined, do not teach or suggest all of the claim limitations, the Examiner has not set forth a prima facie case for obviousness. Thus, the obviousness rejection may be properly withdrawn on this ground.

To establish a prima facie case of obviousness, there must also be a reasonable expectation of success. As discussed above, since neither Devaux *et al.* nor Ashkenazi *et al.* teach or suggest administering an anti-trkC agonist antibody to a mammal having a taxol-induced gut disorder, one skilled in the art would not have a reasonable expectation that an anti-trkC agonist antibody has efficacy in treating taxol-induced gut disorder. It would not have been obvious for one of ordinary skill in the art to combine the teachings of these two references with a reasonable expectation of success in treating taxol-induced gut disorder. On this ground, the obviousness rejection may be properly withdrawn.

In view of the above, claims 1-8 as amended are not obvious over Devaux *et al.* in view of Ashkenazi *et al.* Applicant respectfully requests that rejections under 35 U.S.C. §103 be withdrawn.

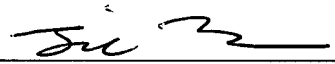
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 514712001600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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